

CLAIMS

1. A pharmaceutical dosage unit for oral, transmucosal or transdermal administration containing at least 10 μg of an androgenic steroid selected from the group consisting of
5 15-hydroxytestosterones, 16-hydroxytestosterones, precursors thereof and mixtures of these hydroxytestosterones and/or their precursors; and a pharmaceutically acceptable excipient.
2. The pharmaceutical dosage unit according to claim 1, wherein the steroid is selected from
10 the group consisting of 15 α -hydroxytestosterone, 15 β -hydroxytestosterone, 16 β -hydroxytestosterone, precursors thereof and mixtures of these hydroxytestosterones and/or their precursors.
3. The pharmaceutical dosage unit according to claim 2, wherein the steroid is selected from
15 the group consisting of 15 α -hydroxytestosterone, 15 β -hydroxytestosterone, precursors thereof and mixtures of these hydroxytestosterones and/or these precursors.
4. The pharmaceutical dosage unit according to claim 3, wherein the steroid is selected from
20 the group consisting of 15 α -hydroxytestosterone, precursors thereof and mixtures of 15 α -hydroxytestosterone and/or these precursors.
5. The pharmaceutical dosage unit according to claim 3, wherein the steroid is selected from
the group consisting of 15 β -hydroxytestosterone, precursors thereof and mixtures of 15 β -hydroxytestosterone and/or these precursors.
- 25 6. The pharmaceutical dosage unit according to claim 2, wherein the steroid is selected from the group consisting of 16 β -hydroxytestosterone, precursors thereof and mixtures of 16 β -hydroxytestosterone and/or these precursors.
- 30 7. The pharmaceutical dosage unit according to any one of claims 1-6, wherein the precursors of the hydroxytestosterones are derivatives of the hydroxytestosterones wherein the hydrogen atom of at least one hydroxyl group has been substituted by an acyl radical of a hydrocarbon carboxylic, sulfonic or sulfamic acid of 1-25 carbon atoms;

tetrahydrofuranyl; tetrahydropyranal; or a straight or branched chain glycosidic residue containing 1-20 glycosidic units per residue.

8. The pharmaceutical dosage unit according to any one of claim 1-7, wherein the dosage unit is an oral dosage unit.
9. The pharmaceutical dosage unit according to claim 8, wherein the dosage unit is a tablet, a capsule, a cachet, a pellet, a pill, a powder or granules.
10. The pharmaceutical dosage unit according to any one of claims 1-9, wherein the dosage unit contains between 20 μg and 1000 mg, preferably between 40 μg and 500 mg of the androgenic steroid.
11. The pharmaceutical dosage unit according to any one of claims 1-10, wherein the dosage unit additionally contains at least 10 μg of a progestogen and/or at least 10 μg of an estrogen.
12. The pharmaceutical dosage unit according to any one of claims 1-11 for use in a method of curatively or prophylactically treating a mammal, said method comprising oral, transmucosal or transdermal administration of the dosage unit to said mammal.
13. The pharmaceutical dosage unit according to claim 12, wherein the method comprises oral administration of the dosage unit to said mammal.
14. The pharmaceutical dosage unit according to claim 12 or 13, wherein the method comprises the administration of the steroid in an average daily amount in the range of 0.5 μg to 1.5 mg per kg of bodyweight, preferably of 1 μg to 1 mg per kg of bodyweight.
15. The pharmaceutical dosage unit according to any one of claims 12-14 for use in a method of treating or preventing androgen deficiency; a method of hormonal contraception; a method of treating or preventing wasting syndrome, anti-retroviral drug induced lipodystrophia, lack of well-being or fatigue in HIV infected individuals; a method of reversing catabolic state caused by a chronic illness, surgical intervention, oncological condition, trauma and/or malnutrition; a method of treating or preventing leydig cell

dysfunction and germinal epithelial damage following cytotoxic chemotherapy; a method of treating or preventing fatigue or maintaining weight, hemoglobine or neutrophil count during or subsequent to cytotoxic chemotherapy or radiotherapy; a method of treating or preventing benign gynaecological disorders; a method of improving libido; a method of
5 treating or preventing delayed puberty; or a method of supporting female-to-male conversion.

16. Use of an androgenic steroid selected from the group consisting of 15-hydroxytestosterones, 16-hydroxytestosterones, precursors thereof and mixtures of these
10 hydroxytestosterones and/or their precursors in the preparation of an oral, transmucosal or transdermal dosage unit.